

K063771

AUG - 9 2007

5 510(k) Summary

| | |
|---------------------------------------|---|
| Submitter: | ARKRAY Factory USA |
| Contact Person: | <p>Tom Speikers Director, Quality Systems and Regulatory Affairs ARKRAY Factory USA, Inc. 5182 W. 76th Street Minneapolis, MN 55439 Phone: 952-646-3168 Fax: 952-646-3110 speikerst@ARKRAYusa.com</p> |
| Date Prepared: | December 11, 2006 |
| Trade Name: | GLUCOCARD X-METER Blood Glucose Monitoring System |
| Classification: | Glucose test system, 21 CFR 862.1345; Class II |
| Product Codes: | CGA, NBW, JJX |
| Predicate Device: | Advance Micro-draw BGM |
| Device Description: | The GLUCOCARD X-METER Blood Glucose Monitoring System consists of a meter, sensor test strips, and control solutions for use as an aid to monitor the effectiveness of diabetes control. |
| Intended Use: | The GLUCOCARD X-METER Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm or palm. Testing is done outside the body (<i>In Vitro</i> diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. |
| Functional and Safety Testing: | <p>A full array of in-house and clinical testing was done consistent with relevant FDA guidances for blood glucose monitoring systems.</p> <p>Bench testing included evaluation of interferences, linearity, linear range, altitude effects, control solution functionality, and analytical precision.</p> <p>Clinical testing included evaluation of accuracy for both finger stick and Alternate Site Testing.</p> <p>Safety testing included evaluation of EMC.</p> |
| Conclusion: | Labeling, bench testing results and clinical testing results support the Indications for Use and the claim of substantial equivalence to the predicate. |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 9 2007

Arkray Factory USA, Inc.
c/o Mr. Tom Speikers
Director, Quality Systems & Regulatory Affairs
5182 W. 76th Street
Minneapolis, MN 55439

Re: k063771

Trade Name: GlucocardX-Meter Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, LFR, JJX
Dated: July 06, 2007
Received: July 10, 2007

Dear Mr. Speikers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K063771

Device Name: GLUCOCARD X-METER Blood Glucose Monitoring System

Indications For Use:

GLUCOCARD X-METER Blood Glucose Monitoring System:

The GLUCOCARD X-METER Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm or palm. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

GLUCOCARD X-METER:

The GLUCOCARD X-METER is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm or palm. GLUCOCARD X-SENSOR Blood Glucose Test Strips must be used with the GLUCOCARD X-METER. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

GLUCOCARD X-SENSOR Blood Glucose Test Strips:

GLUCOCARD X-SENSOR Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm or palm. GLUCOCARD X-SENSOR Blood Glucose Test Strips must be used with the GLUCOCARD X-METER Blood Glucose Meter. Testing is done outside the body (*In Vitro* diagnostic use). They are indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

GLUCOCARD X-METER CONTROL:

For use with GLUCOCARD X-METER Blood Glucose Meter and GLUCOCARD X-SENSOR Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results. Control solutions are available in three levels - Low (L), Normal (N) and High (H).

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K063771